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EXAMINER	
SMITH, TERRI L	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 02/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/674,710	TURCOTT, ROBERT G.	
	Examiner	Art Unit	
	Terri L. Smith	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *24-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10-22-03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 and 30, drawn to a method for identifying, classified in class 607, subclass 7.

II. Claims 24–26, drawn to a system for identifying, classified in class 607, subclass 17.

III. Claim 27, drawn to a method for updating, classified in class 607, subclass 18.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of Groups I and III (process) and Group II (apparatus) are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process as claimed can be practiced by another materially different apparatus not requiring identifying preferred control parameters or updating preferred control parameters, but used solely to continuously diagnose cardiac output signals.

3. Inventions of Group I (combination) and Group III (subcombination) are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because Group I does not require

updating preferred control parameters or detecting a change in patient status. The subcombination has separate utility such as not requiring detecting values representative of transient cardiac performance, but detecting a change in patient status and updating preferred control parameters.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

IN ADDITION TO THE RESTRICTION, A SPECIES MUST BE CHOSEN BELOW.

5. This application contains claims directed to the following patentably distinct species of the claimed invention: If Group I is chosen, Embodiment I or II drawn to a method switching among sets of control parameters during a series of consecutive evaluation periods substantially equal in duration to one another or sufficiently quickly so that hemodynamic feedback systems does not impact the patient before the parameters are switched again, respectively, must be selected. If Group II is chosen, Embodiment III drawn to a system switching among sets of control parameters during a series of consecutive evaluation periods substantially equal in duration to one another or Embodiment IV drawn to an external system or Embodiment V drawn to a system using different sets of control parameters in conjunction with hemodynamic feedback systems must be selected.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, there are no claims that are allowable and generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. During a telephone conversation with Derrick Reed on Tuesday, January 24, 2006 a provisional election was made without traverse to prosecute the invention of Group I, claims 1–23 and 30 and further Embodiment I, claims 1–23. Affirmation of this election must be made by applicant in replying to this Office Action. Claims 24–30 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification

7. The disclosure is objected to because of the following informalities: On page 27, it appears that the word "to" is missing after the word "back" in line 6. And, in line 26, there appears to be a stray right parentheses (")") mark.

Appropriate correction is required.

Claim Objections

8. Claim 2 objected to because of the following informalities: The words "so that" appear back to back in line 2. It appears that these sets of words are redundant and one set should be deleted. Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 4, 7–9, 17, and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims 4 and 7, the term "respiratory cycle" is vague. It is unclear what the Applicant is defining the respiratory cycle to be. Is it a certain number of breaths per a certain length of time? Or is it a given number of breaths per a given number of heart beats/pulse rates? Or is it just one inhalation and one exhalation? Please define.

In claims 7–8, it is unclear if the term "cardiac performance" is the same term as "transient cardiac performance" used in claim 6 from which they depend. It appears that the terms are different and therefore the occurrence of the term "cardiac performance" in claims 7–8 lack antecedent basis for this limitation in the claims.

In claim 17, the phrase "the step of controlling ... while changing control parameters" is unclear and appears to introduce an antecedent basis issue. Do the phrases "switching among sets of control parameters" (claim 1, line 5) and "changing control parameters" (claim 17) mean the same thing? If so, they should be written the same. Examiner interprets these two terms to be different. Consequently, given that claim 17 depends from claim 1, and claim 17 is specifically referring to "the step of controlling" in claim 1, the term "changing control parameters" in the phrase "the step of controlling ..." lacks antecedent basis for this limitation in the claim. Similarly, the phrase "the step of estimating ... control parameter values" lacks antecedent basis for this limitation in the claim (it is not the same as "the step of estimating" in claim 1).

In claim 19, as explained in claim 17, the phrase "the step of detecting values representative of cardiac performance" lacks antecedent basis for this limitation in the claim (claim 1 references "transient cardiac performance").

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1–2, 4–7, 9, 12–21, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Bornzin et al., U.S. Patent 5,549,650.

Bornzin discloses controlling an implantable device to deliver therapy to the heart of a patient while switching among sets of control parameters during a series of consecutive

evaluation periods that are substantially equal in duration to one another (Figs. 9–11; column 18, lines 20–24); detecting values representative of transient cardiac performance corresponding to the different sets of control parameters, and estimating optimal control parameters for maximizing cardiac performance based on the values representative of transient cardiac performance (claim 1) (Figs. 10–11; column 5, lines 5–12; column 19, line 36–column 21, line 30); evaluation periods are sufficiently short so that hemodynamic feedback systems of a patient do not have time to readjust the cardiovascular system of the patient to a substantially equilibrium state before the control parameters are switched again (claim 2) (column 9, lines 21 – 33); evaluation periods are no longer two respiratory cycles each (claim 4) and periods of time over which the values representative of cardiac performance are measured are each set equal to substantially identical portions of a respiratory cycle (claim 7) (Fig. 11); the step of detecting values representative of transient cardiac performance is performed to detect changes in transient cardiac performance from one consecutive evaluation period to another (claim 5) (column 20, lines 3–25); and wherein the step of estimating an optimal set of control parameters is performed based on the changes in transient cardiac performance (claim 5) (Fig. 4; column 19, lines 15–18); the step of detecting changes in transient cardiac performance comprises the steps of: measuring values representative of transient cardiac performance of the heart of the patient during each evaluation period, and determining the difference in transient cardiac performance based on a comparison of the measured values (claim 6) (column 20, lines 35–47); the step of controlling the implantable device to deliver therapy using different sets of control parameters is performed by alternating, from one evaluation period to another, between different sets of selected test control parameters and a set of reference control parameters (claim 9) (column 21, lines 4–30),

cycling through different sets of selected test control parameters to provide for all possible changes between sets of control parameters (claim 12) (column 20, lines 26–34), and cycling through different sets of selected test control parameters to provide for only a sub-set of all possible changes between sets of control parameters (claim 13) (column 20, lines 3–25); the step of determining the difference in transient cardiac performance based on a comparison of the measured values includes the steps of: detecting a value representative of transient cardiac performance during an immediately preceding evaluation period, detecting a value representative of transient cardiac performance during the given evaluation period, and generating a difference value representative of a change in transient cardiac performance between the prior evaluation period and the given evaluation period such that a single difference value is generated for each evaluation period (claim 14) (column 21, lines 4–30); the step of estimating an optimal set of control parameters includes the steps of: associating each difference value with a set of control parameters employed during a corresponding evaluation period, fitting a single/separate curve to the difference values versus associated test parameter values/a set of parameter values; and identifying a set of preferred control parameters providing maximal difference values as indicated by a single/separate curve and averaging a separate sets of preferred control parameters together to yield a single set of control parameters (claims 15–16) (Figs. 10–11; column 21, lines 4–30); the step of controlling an implantable device to deliver therapy while changing control parameters is performed to adaptively adjust control parameters based on resulting changes in cardiac performance (claim 17) (column 20, lines 35–47); and wherein the step of estimating optimal control parameters for use in delivering further therapy is performed to identify control parameters that result in the most positive difference in cardiac performance as compared to all

other control parameter values (claim 17) (column 20, lines 35–44); control parameters include one or more of: pacing base rate; maximum tracking rate; minimum tracking rate, atrioventricular (AV) delay and interventricular delay (claim 18) (Fig. 11); the step of detecting values representative of cardiac performance is performed to detect values representative of one or more of stroke volume, cardiac output, end-diastolic volume, end-systolic volume, ejection fraction, cardiac output index, flow through the mitral valve, maximum rate of change of left ventricular pressure with time, maximum rate of change of aortic pressure with time, mean arterial pressure, arterial pulse pressure, vascular volume, and vascular photoplethysmography (claim 19) (column 19, lines 9–12); the initial step of determining whether to initiate an optimization procedure based on a change in one or more of patient posture, heart rate, activity levels, autonomic tone, and fluid status (claim 20) (Figs. 1, 5–10; column 7, lines 60–62; column 15, lines 18–26); the steps of the method are performed periodically (claim 21) (Figs. 9–10); all steps of the method are performed by the implantable device(claim 23) (Fig. 10; column 21, lines 36–42).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 3 and 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bornzin et al., U.S. Patent 5,549,650.

Bornzin discloses the claimed invention except for the evaluation periods are not longer than 12 seconds each (claim 3) and each set equal to about four seconds (claim 8). It would have been obvious to one having ordinary skill in the art at the time the invention was made to include evaluation periods are not longer than 12 seconds each and each set equal to about four seconds, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). (See MPEP 2144.05).

15. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bornzin et al. as and in view of Baumann, U.S. Patent 5,800,471.

Bornzin does not disclose the step of controlling an implantable device to deliver therapy to the heart of a patient while changing control parameters is performed by an external programmer device. However, Baumann discloses the step of controlling an implantable device to deliver therapy to the heart of a patient while changing control parameters is performed by an external programmer device (column 5, lines column 9, lines 24–30) to arrive at the optimal pacing mode-AV delay interval (column 9, lines 29–30).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the invention of Bornzin to include the step of controlling an implantable device to deliver therapy to the heart of a patient while changing control parameters is performed by an external programmer device, as taught by Baumann to optimize the performance of the implantable device.

Allowable Subject Matter

16. Claims 10–11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terri L. Smith whose telephone number is 571-272-7146. The examiner can normally be reached on Monday - Friday, between 7:30 a.m. - 4:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TLS
February 4, 2006
4 February 2006

GEORGE R. EVANISKO
PRIMARY EXAMINER
2/4/6